

Rulemaking Calendar

HEALTH AND SENIOR SERVICES

THE COMMISSIONER

First Quarter, 2002

January 2002 Through June 2002

The following calendar represents the Department's proposed Rulemaking activities for the period of January 2002 through June 2002. Additionally, the Department is also amending certain sections of its calendar for the Fourth Quarter of 2001 (see 33 N.J.R. 3571). The amendments relating to changes in publication dates are as follows:

<u>Administrative Code Section</u>	<u>Former Publication Month</u>	<u>New Publication Month</u>
N.J.A.C. 8:18-1 through 5	October 2001	February 2002
N.J.A.C. 8:31B	December 2001	January 2002
N.J.A.C. 8:33	December 2001	January 2002
N.J.A.C. 8:33F	November 2001	January 2002
N.J.A.C. 8:33Q	November 2001	March 2002
N.J.A.C. 8:33R	November 2001	July 2002
N.J.A.C. 8:38	October 2001	January 2002
N.J.A.C. 8:38-B	January 2002	February 2002
N.J.A.C. 8:38C-1	February 2002	April 2002
N.J.A.C. 8:38C-1A	February 2002	April 2002
N.J.A.C. 8:43A-12 and 8:43G-6, 34 and 35	November 2001	January 2002
N.J.A.C. 8:43A-31	December 2001	April 2002
N.J.A.C. 8:43D	October 2001	April 2002
N.J.A.C. 8:43E	January 2002	April 2002
N.J.A.C. 8:43E-6.1 through 6.5	November 2001	March 2002
N.J.A.C. 8:43G & 8:43A	December 2001	April 2002
Re: Revised Standards For Renal Dialysis		
N.J.A.C. 8:43G-22	November 2001	March 2002
N.J.A.C. 8:43G-30 & 8:43A-24	December 2001	April 2002

N.J.A.C. 8:43G-(37) 38	November 2001	January 2002
N.J.A.C. 8:52	October 2001	January 2002
N.J.A.C. 8:57	November 2001	February 2002
N.J.A.C. 8:61-1.1, 2.7, 3.1, 4.1	October 2001	February 2002
N.J.A.C. 8:62	December 2001	April 2002

Furthermore, in addition to the new anticipated publication date referred above, the calendar entry for N.J.A.C. 8:57 has been amended to include specific definition and timing requirements that will be set forth in the upcoming rule proposal. The calendar entry for N.J.A.C. 8:43G-37 contains a new publication date and a change in numbering from N.J.A.C. 8:43G-37 to 8:43G-38.

Two proposals not included in the October 1, 2001 rulemaking calendar are added to the calendar for publication in February 2002: N.J.A.C. 8:52, New Jersey State Sanitary Code Chapter XIII – Childhood Lead Poisoning, and N.J.A.C. 8:57-6, Communicable Diseases: Higher Education Immunization (Immunization of Pupils in Schools) – Meningitis Information. On proposal, N.J.A.C. 8:26, Public Recreational Bathing, not included in the October 1, 2001 rulemaking calendar is added to the calendar for publication in March 2002.

Two proposals that appeared in the October 1, 2001 rulemaking calendar were actually published in the New Jersey Register in September 2001, and, therefore, should not have been included in the Department's initial calendar. Those proposals were N.J.A.C. 8:19-2.3 through 2.7 and 2.9, Newborn Screening Program, and N.J.A.C. 8:33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers. Both proposals are omitted from this calendar.

Full Text of the calendar follows (additions in bold face **thus**; deletions indicated in brackets [thus])

HEALTH AND SENIOR SERVICES

Hospital Licensing Standards

N.J.A.C. 8:43G-12

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: July 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend this subchapter to include requirements for hospital policies and procedures for calling emergency department diverts and bypasses and to include various definitions regarding diverts and bypasses.

Hospital Licensing Standards

N.J.A.C. 8:43G-17 and 27

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: April 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend these subchapters to revise and clarify the role and responsibilities of a Quality Improvement Advisory Committee and to amend the types of quality indicators that hospitals must report to the Department.

Children's Hospital Licensing Standards

N.J.A.C. 8:43G-22

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [November 2001] **March 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing new licensing rules for designated children hospitals. The proposed new rule will fulfill the Department's obligation to protect the health and safety of patients requiring treatment at such hospitals by establishing minimum requirements for the organization, physical plant and the provision of special services.

Hospital Licensing Standards

N.J.A.C. 8:43G-30

Ambulatory Care Facilities Licensing Standards

N.J.A.C. 8:43A-24

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5

Anticipated Publication: [December 2001] **April 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend the infection control subchapter in the Hospital Licensing Standards and the Ambulatory Care Facilities Licensing Standards, in order to update these standards to reflect the current practices and technological advances in the field. The proposed amendments will continue to fulfill the Department's obligation to protect the health and safety of patients receiving treatment at hospitals and ambulatory health care facilities by establishing minimum requirements for staffing and patient care services.

Long Term Acute Care Hospital Licensing Standards

N.J.A.C. 8:43G-[37] 38

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [November 2001] **January 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing new rules to establish uniform licensure standards for long term acute care hospitals that provide acute care through a broad spectrum of clinical care services for acutely ill/medically complex patients requiring, on average, a 25 day or greater length of stay. The proposed new rule will fulfill the Department's obligation to protect the health and safety of patients requiring long term acute care services at either a freestanding facility or within the premises of a licensed general hospital (hospital within a hospital).

Criminal Background Checks

N.J.A.C. 8:43I

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-83
Section 2 of P.L. 1997, c.100

Anticipated Publication: March 2002

Synopsis and Purpose of Rulemaking: Rulemaking will require an additional subchapter to include the Criminal History Record and background checks of applicants for Nurse Aide and Personal Care Assistant recertification.

New Jersey State Sanitary
Code Chapter XIII – Childhood Lead Poisoning
N.J.A.C. 8:51

Authorized by: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 24:14A-1 et seq., 26:1A-7, 26:2Q-1 et seq.
and 26:2-137 et seq.

Anticipated Publication: February 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing an amendment to Chapter XIII of the NJ State Sanitary Code – Childhood Lead Poisoning. This Chapter contains the rules that govern local health department activities when children are identified with elevated blood lead levels. The proposed amendment will add a penalty section to the existing rule. Chapter XIII, as currently written, does not contain a penalty clause for violations of its requirements and relies upon the standard penalties for all chapters of the State Sanitary Code that are set forth in N.J.S.A. 26:1A-10. This amendment will be proposed because the Administrative Office of the Courts, and the Attorney General's office has informed the Department that the general penalty clause found in the statute is no longer sufficient and that each chapter must have its own penalty section.

Public Health Practice Standards Of Performance For Local Boards Of Health

N.J.A.C. 8:52

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:1A-15, 26:3A2-1 et seq.

Anticipated Publication: [October 2001] **January 2002**

Synopsis and Purpose of Rulemaking: Repeal and propose new rules; establish standards of performance for public health services pursuant to legislative intent as set fourth in the Local Health Services Act and Local Boards of Health by designing those activities which are required by all local boards of health and which shall build local public health capacity and encourage the development of an integrated systems approach for local public health.

Communicable Disease

N.J.A.C. 8:57

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:4-2 et seq.

Anticipated Publication: [November 2001] **February 2002**

Synopsis and Purpose of Rulemaking: [Propose to amend rules; amending existing rules that set forth the standards for communicable, environmental and occupational disease prevention and control to include standards for higher education meningococcal vaccination, require health officers to file completed outbreak investigation reports, modify physician reporting to include occupational poisoning and carpal tunnel syndrome, and to include changes that were proposed to the final rule published in the New Jersey Register on September 20, 2000 that were considered substantive and required and additional public comment period.] **The proposal will amend existing rules that set forth the standards for communicable, environmental and occupational disease prevention and control to include standard for higher education meningococcal vaccination, require health officers to file completed outbreak investigation reports, modify physician reporting to include occupational poisoning and carpal tunnel syndrome, and correct other minor needed changes. The proposal also adds the term “clinical nurse specialists” clarifies the Hib vaccine timing requirement, permits the recently licensed two dose hepatitis B schedule, and makes other minor language changes.**

Communicable Diseases
Immunization of Pupils in Schools
N.J.A.C. 8:57-4

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner
Department of Health and Senior Services

Authority: N.J.S.A. 26:1A-7

Anticipated Publication: June 2002

Synopsis and Purpose of Rulemaking: The proposed new rule will require varicella vaccine receipt or proof of varicella immunity of children in child care centers and pupils entering Kindergarten/Grade 1 by September 1, 2003 or no later than September 1, 2004.

Communicable Diseases

**Higher Education Immunization (Immunization of Pupils in Schools)-
Meningitis Information**

N.J.A.C. 8:57-6

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 18A:61D-1 et seq. and 26:1A-7

Anticipated Publication: February 2002

Synopsis and Purpose of Rulemaking: The proposal will ensure the provision of meningitis information to new college students at four-year colleges and universities in New Jersey.

Acquired Immunodeficiency Syndrome

N.J.A.C. 8:61-1.1, 2.7, 3.1 and 4.1

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner
Department of Health and Senior Services

Authority: N.J.S.A. 26:1A-15 and 26:5c-20

Anticipated Publication: [October 2001] **February 2002**

Synopsis and Purpose of Rulemaking: Amendments to N.J.A.C. 8:61-1.1 provide an updated definition of Acquired Immunodeficiency Syndrome. Amendments to N.J.A.C. 8:61-2.7 provide for a new toll free phone number to obtain applications for the AIDS drug distribution program. Proposed amendments to N.J.A.C. 8:61-3.1(a) will require a physician to offer HIV testing to a pregnant woman even if the physician is aware that testing has already been offered and refused. N.J.A.C. 8:61-3.1(f) will allow the Department or its designee to contact an HIV positive woman or her infant's pediatrician for follow-up on the HIV status or HIV related care of the infant. This amendment will allow the pediatrician to implement treatment regimens to further reduce transmission to the child. Amendments to N.J.A.C. 8:61-4.1 would add circumstances under which a child's HIV/AIDS records may be disclosed in the absence of prior written consent by the Division of Youth and Family Services. The amendment broadens the category of full time caregivers who can be informed, on a need to know basis, of a child's HIV/AIDS records.

Standards For Lead Certification

N.J.A.C. 8:62

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2Q-1 et seq.

Anticipated Publication: [December 2001] **April 2002**

Synopsis and Purpose of Rulemaking: Propose to amend rules; amend existing rules that set forth the standards that govern the certification and training of the lead evaluation and abatement industry to reflect changes made in the United States Environmental Protection Agency (EPA) Lead Training Model Program and to include complementary rules being developed by the Department of Community Affairs.

New Jersey Commission On Spinal Cord Research: Operation Of The New Jersey Commission On Spinal Cord Research Central Spinal Cord Injury Registry Health Care Provider Reporting Requirements
N.J.A.C. Section to be determined

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 52:9E-5, 52:9e-8(b)

Anticipated Publication: June 2002

Synopsis and Purpose of Rulemaking: Proposed new rules will be established necessary for the operation of the New Jersey Commission on Spinal Cord Research, and will establish for health care providers the reporting requirements that are necessary for the Central Spinal Cord Injury Registry.

The Commission whose responsibility is to solicit, review, approve and administer support of research grants, promote development within the State of New Jersey of spinal cord research projects that are focused on treatments and cures, establish and maintain a Central Spinal Cord Injury Registry of persons who sustain spinal cord injuries other than through disease, and compile a directory of spinal cord research projects being conducted within the State of New Jersey.

Genetic Privacy And Informed Consent

N.J.A.C. 8:18-1, 2, 3, 4, 5

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: P.L. 1996, c. 126, ss. 6 through 10 (N.J.S.A. 10:5-44 through 49)

Anticipated Publication: [October 2001] **February 2002**

Synopsis and Purpose of Rulemaking: The Genetic Privacy Act, P.L. 1996, c. 126 (as codified, N.J.S.A. 10:5-44 through 49 et seq., effective November 19, 1996) ("the Act") intends to provide a right to informed consent before genetic testing, protection for the confidentiality of individual genetic information, and protection against certain discrimination and discriminatory practices. The proposed new rules intend to implement sections 6 through 10 of the Act (as codified, N.J.S.A. 10:5-44 through 49) that require the Commissioner of the Department of Health and Senior in consultation with the Commissioner of the Department of Banking and Insurance, to establish regulations regarding informed consent and the collection, disclosure and retention of genetic information generally.

Sanitation In Retail Food Establishments

N.J.A.C. 8:24

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:1A-7

Anticipated Publication: April 2002

Synopsis and Purpose of Rulemaking: Propose to amend rules; amend existing rules (Chapter XII of the New Jersey Sanitary Code) for the purpose of compliance with federal requirements and technological improvements in the food handling process.

Veterinary Public Health

Municipal Notification for Pet Licensing of All Sales or Adoptions of Dogs and Cats from Licensed Animal Facilities

N.J.A.C. 8:23A-1.10

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 4:19-15.14

Anticipated Publication: June 2002

Synopsis and Purpose for Rulemaking: The proposed new rule will increase the effectiveness of municipal dog licensing efforts by requiring pet shops and shelters to notify the municipality of a sale or adoption by one of its residents.

Public Recreational Bathing

N.J.A.C. 8:26

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services.

Authority: N.J.S.A. 26:1A-7 and 26:4A-7.

Anticipated Publication: March 2002.

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing rule amendments for the purpose of complying with EPA's National Beach Guidance and Performance Criteria for Recreational Waters. Specifically, we will be proposing changes from the use of fecal and total coliform to Enterococcus. Other changes will be made for clarification.

Hospital Financing

N.J.A.C. 8:31B

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [December 2001] **March 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing amendments to the requirements governing submission of hospital cost reports to require a separate cost report for each licensed hospital eligible for charity care subsidies. In addition, the Department intends to introduce amendments to comply with the recommendations set forth in the New Jersey Supreme Court Matter *Northwest Covenant Medical Center v. Fishman* (decided April 23, 2001), 167 *N.J.* 123.

Certificate of Need: Application and Review Process

N.J.A.C. 8:33

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [December 2001] **January 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing significant revisions to the certificate of need application and review manual. The last major revision of this rule was nine years ago. The intended changes will bring these rules into conformance with the most recent statutory changes made to the process.

Certificate of Need: Application and Review Process

N.J.A.C. 8:33

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: May 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing revisions to the certificate of need application and review manual to clarify general hospital transfer of ownership requirements.

Certificate of Need and Licensure: Regionalized Perinatal Services and Maternal and Child Health Consortia

N.J.A.C. 8:33C

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: July 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing revisions to N.J.A.C. 8:33C to reflect recommendations contained in the most recent evaluation report of the Maternal and Child Health Consortia.

Certificate of Need: Long Term Acute Care Hospitals

N.J.A.C. 8:33F

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [November 2001] **January 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing new rules to establish certificate of need requirements for all new long term acute care hospitals and for all licensed long term acute care hospitals proposing to alter their licensing bed complement in the future. The proposed new rule will enhance the quality of care and improve outcomes for high acuity, long-stay acute care patients by providing services in a more interdisciplinary and clinically specialized setting.

**Policy Manual for Planning and Certificate of Need Reviews of Long Term
Care Facilities and Services**

N.J.A.C. 8:33H

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: May 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior
Services is proposing to revise N.J.A.C. 8:33H to reflect changes in requirements
for the certificate of need review of specialized long term care beds and services.

**Certificate of Need: Rehabilitation Hospitals and Comprehensive
Rehabilitation Services**

N.J.A.C. 8:33M

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: September 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing revisions to N.J.A.C. 8:33M to amend the need methodology and geographic planning areas for the addition of new/expanded rehabilitation beds and services.

Certificate of Need: Solid Organ Transplantation Services

N.J.A.C. 8:33Q

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [November 2001] **March 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to readopt the rules governing the criteria for review of applications for additional solid organ transplantation services. The only revision to the rule will be to permit existing kidney transplant providers to also perform pancreas transplantation without applying for additional Certificate of Need approval. This amendment will be proposed because scientific advances have improved the clinical effectiveness of simultaneous kidney/pancreas transplantation. Prior to beginning pancreas transplant services the provider will have to obtain licensing approval.

**Certificate of Need: Planning and Certificate of Need Reviews of
Psychiatric Health Care Facilities and Services**

N.J.A.C. 8:33R

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [November 2001] **July 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to readopt without change the rules governing the criteria for review of applications for additional inpatient psychiatric services.

Health Maintenance Organizations

N.J.S.A. 8:38

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:23-1 et seq.

Anticipated Publication: [October 2001] **January 2002**

Synopsis and Purpose of Rulemaking: Readoption in accordance with Executive Order 66 (1978) and N.J.S.A. 52:14B-5.1. To maintain in effect the current rules regulating health maintenance organizations at N.J.A.C. 8:38, with minor modifications, or modifications otherwise required pursuant to changes in case law. Specifically, subchapter 16, regarding claims payments, and all definitions and references related to subchapter 16, will be deleted in light of enactment of P.L. 1999, c.154, commonly referred to as "HINT," which repealed the principle statute on which subchapter 16 was based, and established regulatory authority regarding HMO claims with the Department of Banking and Insurance (DOBI). That agency now has adopted rules at N.J.A.C. 11:22-1 addressing claims payment issues. In addition, several citations and cross-references will be corrected, or added for purposes of clarification, or simplification. Thus: the list of "health wellness promotion" services that must be covered, and the dollar figures associated therewith, will be removed, and substituted by a reference to DOBI's rules specific to the subject matter at N.J.A.C. 11:22-2 instead; reference will be made to N.J.A.C. 11:4-49 regarding diabetes benefits; a reference will be added to N.J.A.C. 8:38-5.7 to the formulary rules at N.J.A.C. 8:38-18; references to acts and chapter laws are being substituted by references to statutory codifications to assure consideration of amendments that have or may occur to the statutory provisions; a reference to N.J.S.A. 26:21-4.21 will be added relative to the provision of skilled nursing care; and, certain additional citations will be corrected. Certain terms will be altered to reflect changes in terminology that have occurred over time in other referenced regulations. Finally, permissive language allowing HMOs to pursue subrogation will be removed to avoid any real or perceived conflicts with *Perriera v. Rediger, et al.* Dkt. No. A-145-99, decided June 26, 2001.

Organized Delivery Systems

Proposed New Rules: N.J.A.C. 8:38B

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 17:48H-32

Anticipated Publication: [January 2002] **February 2002**

Synopsis and Purpose of Rulemaking: These proposed new rules are being promulgated in accordance with P.L. 1999, c. 409 (codified as N.J.S.A. 17:48H-1 et seq.), hereinafter referred to as “the Act.” The Act creates a new entity referred to as an “organized delivery system,” or “ODS”. An ODS is an entity that, among other things, has the capacity to contract with insurers, health maintenance organizations, and medical hospital and health service corporations (collectively, “carriers”), to provide or arrange for the provision of health care services to individuals covered under one or more of a carrier’s health benefits plans delivered in New Jersey. The primary intent of the Act, and the proposed new rules, is to heighten the accountability of those entities engaged in the delivery or allocation of health care services to New Jersey’s citizens, and the financing of those services.

These proposed rules interpret the definitions established by the Act; establish procedures and standards for application to be a certified ODS; establish procedures and standards by which the Department will review an application for certification; establish procedures and standards for modification, renewal and revocation of a certification; establish standards for resolution of an ODS’ business in the event of revocation; and, establish fees relevant to certification applications, modifications and renewals. These proposed new rules also establish the standards that an ODS applying for a license must meet in order for the Department to make a positive recommendation to Department of Banking and Insurance with respect to the licensing application.

Managed Care Plans: Hemophilia Coverage

N.J.A.C. 8:38C-1

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:25-10.1 through 10.3

Anticipated Publication: [February 2002] **April 2002**

Synopsis and Purpose of Rulemaking: Establishment of standards with which
carriers must comply with respect to administration of cover for hemophilia
treatment.

Designation of Hemophilia Health Care Providers

N.J.A.C. 8:38C-1A

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:25-10.1 through 10.3

Anticipated Publication: [February 2002] **April 2002**

Synopsis and Purpose of Rulemaking: Establishment of standards and procedures for designating certain providers as hemophilia treatment providers and laboratories.

Managed Care Plans: Universal Provider Participation Application

N.J.A.C. 8:38C-2

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2S-7.1

Anticipated Publication: May 2002

Synopsis and Purpose of Rulemaking: These proposed new rules will establish a standard form that carriers using networks of health care providers must accept from health care providers seeking to participate in the carrier's network. These proposed new rules will also establish a standard renewal form as well. The intent is to simplify the credentialing and re-credentialing paperwork for health care providers.

**Managed Care Plans: Managed Health Care Consumer Assistance
Program**
N.J.A.C. 8:38C-3

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2S, and 19 through 25

Anticipated Publication: July 2002

Synopsis and Purpose of Rulemaking: These proposed new rules will establish standards regarding the Managed Health Care Consumer Assistance Program (MHCCAP). The MHCCAP is intended to provide education and assistance to consumers with questions or concerns about their health care coverage. The MHCCAP is designed to help consumers better understand their rights and responsibilities, the functions of State and Federal agencies that regulate managed care, and assist consumers in finding and navigating appropriate complaint and appeal processes. The MHCCAP may be operated through contracts with other entities. The proposed new rules will also address the notice requirements that carriers are required to provide to subscribers regarding the MHCCAP.

Pain Management Rules

N.J.A.C. 8:39

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-12.8

Anticipated Publication: February 2002

Synopsis and Purpose of Rulemaking: State-level implementation of already-existing federal requirement that facilities assess, manage and treat patient/resident pain.

Emergency Medical Services

**N.J.A.C. 8:40 Manual of Standards for Licensure of Mobility
Assistance Vehicle and Ambulance Services**

N.J.A.C. 8:40A Emergency Medical Technician Training

N.J.A.C. 8:41 Mobile Intensive Care Program

N.J.A.C. 8:41A EMT-First Responder- D Cardiac Defibrillation

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authorities: N.J.A.C. 8:40 - N.J.S.A. 30:4D-6.4 and 6.6 and N.J.S.A. 26:2H-1
N.J.A.C. 8:40A - N.J.S.A. 26:2K-39 through 47 and N.J.S.A. 26:2K-
54 through 62
N.J.A.C. 8:41-N.J.S.A. 26:2K-7 through 20 and 26:2K-35 through
38
N.J.A.C. 8:41A - NJSA 26:2K-7 through 20

Anticipated Publication: April 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to repeal these rules and adopt new ones. As the rules now exist, Chapter 40, Manual of Standards for Licensure of Mobility Assistance Vehicle and Ambulance Services, contains the rules that govern mobility assistance vehicles (formerly known as invalid coach services), basic life support ambulances, transport ambulances (which no longer exist as a licensed service within New Jersey) and advanced life support helicopter ambulances (for example Northstar and Southstar). Chapter 41, Mobile Intensive Care Programs, contains the rules that govern advanced life support mobile intensive care units and EMT-Paramedics.

Substantial changes to the rules include incorporating the advanced life support portion of Chapter 40 (that is, the subchapter governing helicopter ambulances, which we now propose to call aero-medical units) into Chapter 41, and the addition of new rules that govern the licensure, inspection and enforcement of specialty care transport providers. The new Chapter 41 would then serve as the repository for all advanced life support service providers (that is, mobile intensive care programs, specialty care transport providers and aero-medical service providers). The removal of the language governing helicopter ambulances and transport ambulances from Chapter 40 necessitates an amendment of that chapter period. Chapter 40A, Emergency Medical Technician Training, will need to be amended to make Chapters 40, 40A and 41 consistent. Terminology in the rules will be revised for consistency with that of the National Registry of Emergency Medical Technicians (NREMT).

Ambulatory Care Facilities Licensing Standards

N.J.A.C. 8:43A

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: May 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend N.J.A.C. 8:43A in order to remove notice of certificate of need requirements since no ambulatory care services currently require certificate of need approval.

Hospital Licensing Standards

N.J.A.C. 8:43G-6, 34 and 35

Ambulatory Care Facility Licensing Standards

N.J.A.C. 8:43A-12

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5

Anticipated Publication: [November] **January 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend N.J.A.C. 8:43G, Hospital Licensing Standards, and N.J.A.C. 8:43A, Ambulatory Care Facilities Licensing Standards, to establish uniform licensure standards pertaining to surgery, anesthesia and postanesthesia care for general and special hospitals in New Jersey. These proposed amendments update and reflect the current practice and technology that will not only afford providers with the ability to provide care, but also preserve the quality of care.

Ambulatory Care Facilities Licensing Standards
N.J.A.C. 8:43A-31

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5

Anticipated Publication: [December 2001] **April 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing amend N.J.A.C. 8:43A, Standards for Licensure of Ambulatory Care Facilities, in order to revise licensure standards for health care services not specifically addressed in these rules. These rule amendments clarify that the general portions of the rules apply to all ambulatory care facilities and would also allow the Commissioner to impose additional requirements beyond the requirements contained in these rules, in order to protect the health and safety of the inhabitants of the State.

Ambulatory Care Facilities Licensing Standards
N.J.A.C. 8:43A-31

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5

Anticipated Publication: [December 2001] **April 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing amend N.J.A.C. 8:43A, Standards for Licensure of Ambulatory Care Facilities, in order to revise licensure standards for health care services not specifically addressed in these rules. These rule amendments clarify that the general portions of the rules apply to all ambulatory care facilities and would also allow the Commissioner to impose additional requirements beyond the requirements contained in these rules, in order to protect the health and safety of the inhabitants of the State.

Pediatric Community Transitional Home Licensing Standards

N.J.A.C. 8:43D

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [October 2001] **April 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to establish uniform licensure standards for pediatric community transitional homes which are intended to promote a coordinated array of supportive health care, personal and social services for medically fragile children. The proposed new rule establishes appropriate minimum requirements for the provision of pediatric community transitional care and protection of resident health, safety and general welfare.

General Licensure Procedures and Enforcement of Licensing Regulations

N.J.A.C. 8:43E

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: May 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend N.J.A.C. 8:43E to bring it into conformance with the most recent statutory changes made to the certificate of need process and to clarify track record requirements for general hospital transfers of ownership.

General Licensure Procedures and Enforcement of Licensing Regulations

N.J.A.C. 8:43E

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5

Anticipated Publication: [January] April 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend N.J.A.C. 8:43E, General Licensure Procedures and Enforcement of Licensure Regulations, to establish pain management care for all types of health care facilities. These rules will contain pain management services, policies to protect patient rights for pain management and procedures for overseeing and monitoring the delivery of these services.

Safety Needle Rules

N.J.A.C. 8:43E-6.1 through 6.5

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-5.10

Anticipated Publication: [November 2001] **March 2002**

Synopsis and Purpose of Rulemaking: Rulemaking will require all licensed health care facilities to utilize syringes and other sharps with integrated safety features in order to protect health care workers from exposure to bloodborne pathogens.

Hospital Licensing Standards

N.J.A.C. 8:43G

Ambulatory Care Facilities Licensing Standards

N.J.A.C. 8:43A

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: [December 2001] **April 2002**

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing amendments to N.J.A.C. 8:43A and 8:43G to update the licensure standards for the operation of renal dialysis services at hospitals and ambulatory care facilities. The proposed revisions will continue to fulfill the Department's obligation to protect the health and safety of patients requiring renal dialysis treatment by providing minimum requirements for the organization, staffing, physical plant and patient care services of renal dialysis facilities.

Hospital Licensing Standards

N.J.A.C. 8:43G-5

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: July 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend this subchapter to revise and expand requirements for hospital disaster planning.

Hospital Licensing Standards

N.J.A.C. 8:43G-4.1 and 5.6

Authorized By: George T. DiFerdinando, Jr., MD, MPH, Acting Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq.

Anticipated Publication: April 2002

Synopsis and Purpose of Rulemaking: The Department of Health and Senior Services is proposing to amend these sections to require that an alleged or possible violation of patient rights is a reportable event to the Department.

List of Interchangeable Drug Products

N.J.A.C. 8:71

Authorized By: Drug Utilization Review Council, Robert G. Kowalski, Acting Executive Director

Authority: N.J.S.A. 24:6E-6(b)

Synopsis and Purpose of Rulemaking: The List of Interchangeable Drug Products is a generic formulary, or list of acceptable generic drugs, that unless otherwise directed, pharmacists must use in place of brand-name prescription medicines, passing along the resultant savings to consumers. The Council proposes additions, deletions and changes upon receipt of petitions from interested manufacturers. These petitions are made pursuant to receipt of forms and other data the Council has established as criteria for approval. As the content of a particular proposal is dependent upon the petitions the Council receives, the specifics of future proposals cannot be forecast. Forms and other requirements are available on the following web site www.state.nj.state.us/health/mgmt/drugutil/htm or by request to:

Robert G. Kowalski, R.Ph.
Acting Executive Director
Drug Utilization Review Council
New Jersey Department of Health and Senior Services
Room 501, PO Box 360
Trenton, NJ 08625-0360
609-292-4029
Fax: 609-984-2218

Publication Dates: The Council anticipates that notices of proposal as described above will be published in the New Jersey Register during the following months:

February 2002
April 2002
June 2002